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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|------------------------|------------------|
| 09/885,478 | 06/20/2001 | John A. Salon | 57453-A-PCT-US/JPW/AJW | 5447 |

7590 03/24/2003

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O HARA, EILEEN B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1646 | |

DATE MAILED: 03/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/885,478 | SALON ET AL. |
| | Examiner | Art Unit |
| | Eileen O'Hara | 1646 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 december 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 169-188 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 169-172 and 175-188 is/are rejected.
- 7) Claim(s) 173 and 174 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8.9</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. Claims 169-188 are pending in the instant application. Claims 1-11, 32-34, 41, 43, 47, 83, 96 and 97 have been canceled as requested by Applicant in Paper Number 13, filed Dec. 16, 2002.

Claims 168-188 are currently under examination.

Election/Restrictions

2. In response to the restriction requirement, Applicants have canceled the previously pending claims and added new claims 168-188, which correspond to original Group I.

Information Disclosure Statement

3. The second supplemental information disclosure statement filed Sept. 23, 2002, Paper No. 12, is in the file. However, the PTO-1449 and the references are missing in the file. Therefore it is requested that Applicants submit a copy of the references for consideration with their response to this Office Action.

Advisory Information/Priority

4. The amendment to update the priority in Applicant's preliminary amendment A, Paper No. 1/12, filed Nov. 28, 2001, was not entered because there was no marked-up version of the amendment. It is requested that Applicants submit a new amendment to update the priority.

Claim Objections

- 5.1 Claims 184 and 185 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 184 is drawn to a mammalian cell, but is dependent upon claim 182, which is drawn to a non-mammalian cell.
- 5.2 Claim 169 is objected to because of the following informalities: the full name of the protein (melanin concentrating hormone 1) receptor should be spelled out in the independent claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 173 and 180 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants referral to the deposit of plasmid pEXJ.HR-TL231 on page 37 of the specification is an insufficient assurance that all of the conditions of 37 CFR sections 1.801 through 1.809 have been met. If the deposits were made under the provisions of the Budapest

Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State. Additionally, amendment of the specification to recite the complete name and address of the depository, which has changed, is required.

The correct address is:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

Correction is required on page 37, line 20 of the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7.1 Claims 169-172, 175-179, 181-188 are rejected under 35 U.S.C. 102(e) as being anticipated by Bergsma et al., US Patent No. 6,033,872, priority date Dec. 11, 1996 (cited by Applicants).

Claims 169-172, 175-179, 181-188 encompass an isolated nucleic acid encoding an MCH1 receptor of SEQ ID NO: 2 or a mutant, analog or homolog thereof, wherein the nucleic acid is DNA, cDNA or RNA, vector which may be baculovirus or plasmid, host cells (non-mammalian or mammalian or insect) which may be Xenopus oocyte, insect cell, membrane preparation, or wherein the mutant human mutant receptor comprises the amino acid sequence set forth in SEQ ID NO: 28.

Bergsma et al. discloses a nucleic acid (SEQ ID NO: 1) encoding a protein (SEQ ID NO: 2) identified as 11cb splice variant that is 100% identical to amino acids 70-422 of SEQ ID NO: 2 of the instant application and 100% identical to the protein of SEQ ID NO: 28 of the instant application.

On page 32 of the specification, analogs are described as:

Art Unit: 1646

Nucleic acid analogs of the human MCH1 receptor genes differ from the human MCH1 receptor gene described herein in terms of the identity or location of one or more nucleic acid bases (deletion analogs containing less than all of the nucleic acid bases shown in FIG. 1 or contained in plasmid pEXJ.HR-TL231, substitution analogs wherein one or more nucleic acid bases shown in FIG. 1 or contained in plasmids pEXJ.HR-TL231 are replaced by other nucleic acid bases, and addition analogs, wherein one or more nucleic acid bases are added to a terminal or medial portion of the nucleic acid sequence) and which encode proteins which share some or all of the properties of the proteins encoded by the nucleic acid sequences shown in FIG. 1 or contained in plasmid pEXJ.HR-TL231.

According to this, the protein of Bergsma et al. meets the limitations of an analog or mutant of SEQ ID NO: 2 of the instant application. Bergsma et al. also teach that the nucleic acid can be DNA, cDNA or RNA, (column 3, lines 22-29), vectors such as baculovirus and plasmids in which the nucleic acid is operatively linked, host cells such as yeast, COS, insect Sf9 cells, Xenopus oocytes (column 13, line 39 to column 16, line 24 and column 23, lines 18-25) and membrane preparations from the cells (column 23, lines 40-49). Therefore, Bergsma et al. anticipates the claims.

7.2 Claims 169-172, 175-179, 181-188 are rejected under 35 U.S.C. 102(a) as being anticipated by Bergsma et al., EP 848 060.

Claims 169-172, 175-179, 181-188 encompass an isolated nucleic acid encoding an MCH1 receptor of SEQ ID NO: 2 or a mutant, analog or homolog thereof, wherein the nucleic acid is DNA, cDNA or RNA, vector which may be baculovirus or plasmid, host cells (non-mammalian or mammalian or insect) which may be Xenopus oocyte, insect cell, membrane preparation, or wherein the mutant human mutant receptor comprises the amino acid sequence set forth in SEQ ID NO: 28.

Bergsma et al. discloses a nucleic acid (SEQ ID NO: 1) encoding a protein (SEQ ID NO: 2) identified as 11cb splice variant that is 100% identical to amino acids 70-422 of SEQ ID NO:

2 of the instant application and 100% identical to the protein of SEQ ID NO: 28 of the instant application. Bergsma et al. also teach that the nucleic acid can be DNA, cDNA or RNA, (page 7, lines 44-47), vectors such as baculovirus and plasmids in which the nucleic acid is operatively linked, host cells such as yeast, COS, insect Sf9 cells, Xenopus oocytes (page 9, line 54 to page 1, line 3 and 23, lines 18-25) and membrane preparation from the cells (page 16, lines 15-18). Therefore, Bergsma et al. anticipates the claims.

Conclusion

- 8.1 Claims 169-172 and 175-188 are rejected.
- 78.2 Claims 173 and 174 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner



YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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